A system for performing peritoneal dialysis

Field of the invention

The present invention relates to systems for performing peritoneal dialysis on a patient and more precisely to such systems which include a liquid distribution system forming a distinct element.

State of the art

Peritoneal dialysis systems as defined above are described in the following patent documents : EP 0 790 841 B1, EP 0 695 397 B1, EP 0 852 953 B1, EP 0 694 125 B1, EP 0 686 237 B1, EP 0 471 000 B1, EP 0 332 690 B1, EP 0 262 182 B1, EP 0 259 464 B1 and EP 1 195 171 A2.

Summary of the invention

An objective of the present invention is to provide an improved peritoneal dialysis system and in particular an improved liquid distribution system.

This objective and many others are achieved with the system as defined in claim 1 and 38.

Preferred embodiments of the invention are defined in dependent claims 2 to 37 and 40 to 46.

Several advantages result from the invention, in particular :

- simpler, and therefore more efficient, liquid distribution system which may include only two distinct cavities,
- possibility to use a peristaltic pump, in particular a rotatable peristaltic pump,
- possibility to use an unidirectional pump which results in a higher precision and a longer life time,
- possibility to fix the liquid distribution system and the pump together, alternatively with vibration attenuating means,
- possibility to use a flexible membrane which covers the chambers and which include valve elements,
- the membrane may be molded,
- part of a pressure sensor can be incorporated in the membrane.

Those and other advantages will be better understood in the detailed description of the invention exemplified here below, together with the following figures.

Short description of the figures

Figure 1 shows in a schematic way the principle of the invention

Figure 1A shows the "fill" phase

Figure 1B shows the "drain" phase

Figure 2 illustrates a first embodiment of the invention (liquid distribution system)

Figure 3 illustrates a second embodiment (disposable cartridge) including a warmer chamber

Figure 4 shows the embodiment of figure 3 in a transparent view

Figure 5 shows the back side of the embodiment of figure 3 (disposable cartridge)

Figure 6 illustrates the disposable cartridge of figure 3 with the complete tubing set

Figure 7 shows an embodiment with the rotative parts (rollers) integrated on the cycler

Figure 8 shows the embodiment of figure 7 without the rollers

Figure 9 the disposable cartridge in two parts allowing to absorb pump vibrations

Figure 10 shows a cycler without the cartridge insertion slot

Figure 11 illustrates a disposable cartridge opened showing the peritoneal pump

Figure 12 is an upper view of an elastic molded membrane

Figure 13 is a bottom view of the membrane of figure 12

Figure 14 shows a membrane clipping system

Figure 15 shows the cycler of figure 10 in an open state

Figure 16 shows a cartridge loader

Figure 17 shows the cycler of figure 10, the insertion slot opened with the cartridge

Figure 18 shows the cycler of figure 10, the insertion slot closed with the cartridge

Figure 19 shows a front view of a valve

Figure 20 shows a front view of a pressure sensor

Figure 21 shows a pump race

Figure 22 shows a valve actuator and a membrane clipping system

Figure 23 shows a warmer

Figure 24 shows a warmer casing

Figure 25 is a table showing drain profiles

Figure 26 shows another embodiment of the invention

Figure 27 shows another embodiment of the invention

Figure 28 shows a molded frame in an upper view

Figure 29 shows the molded frame of figure 28 in a bottom view

Figure 30 shows the molded frame of figure 28 fixed to a liquid distribution system

Figure 31 shows the system of figure 30 in a cross section

Figure 32 shows a flow preventing system

Figure 33 shows an exploded upper view of another embodiment of the invention

Figure 34 shows the embodiment of figure 33 in a bottom view

Figure 35 shows the embodiment of figures 33 and 34 in an assembled view

Figure 36 shows a cross section of the embodiment of figure 35

Figure 37 shows an enlarged view of a part of the embodiment of figure 33.

<u>Numerical references used in the drawings</u>

1. Pump
2. Liquid distribution system (cartridge)
3. Supply means (bag)
4. Patient
5. Patient line
6. Drain collector
7. First hub chamber
8. Second hub chamber
9. Liquid supply port with valve
10. Patient port with valve
11. Drain port with valve
12. Roller separator
13. Membrane
14. Membrane frame
15. Pressure sensor cavity (patient)
16. Patient port with valve (warmer chamber)

17. Warmer chamber
18. Patient port with valve (first hub chamber)
19. Warmer port
20. Roller element
21. Pump race
22. Roller
23. Tube connector for warming enter line
24. Liquid supply line
25. Drain line
26. Pump inlet
27. Pump outlet
28. Warmer pouch
29. Warmer enter line
30. Warmer exit line
31. Membrane pressure sensor area
32. Retaining element for pressure sensor
33. Clip cavity
34. Actuator
35. Clip plunger
36. Pressure sensor cavity (first hub chamber)
37. Pump flexible tube
38. Warmer port with valve
39. Membrane actuator clip
40. Membrane pressure volute
41. Cartridge loader
42. Pump motor + coder
43. Air sensor
44. Pressure sensor
45. Pump casing
46. Cartridge loader shaft
47. Cartridge loader frame
48. Cartridge loader linear cam
49. Cartridge loader motor

50. Cartridge insertion slot
51. Cycler
52. Cartridge motor shaft
53. Tube connector for supply line
54. Tube connector for drain line
55. Tube connector for warmer exit line
56. Pump enter line
57. Pump exit line
58. Sensor pressure housing
59. Sealing flange
60. Clamping member
61. Shaft retaining member
62. Shaft
63. Retaining lip
64. Clamping slot
65. Opening
66. Releasing slot
67. Rigid plate
68. Pin
69. Membrane holes
70. Rigid plate holes
71. Cavity
72. Groove
73. Flange

Detailed description of the invention

The peritoneal dialysis system according to the invention is shown in a schematic way in figure 1. It includes a pump **1**, a liquid distribution system **2** (also named cartridge) comprising a first hub chamber **7** and a second hub chamber **8**. The first chamber **7** includes a pump inlet **26** connected to the pump **1** via a pump enter line **56**, a liquid supply port **9** with valve connected to supply means, e.g. to bags **3**, via a liquid supply line **24** and a patient port **10** with valve connected to a patient **4** via a patient line **5**. The second chamber **8** includes a pump outlet **27** connected to the pump **1** via a pump exit line **57**, a drain port **11** with valve connected to a drain collector **6** via a drain line **25** and a patient port **18** with valve connected to a patient **4** via a patient line **5**.

Figure 1A shows the "fill" phase where liquid is supplied to the patient **4** from and through the following elements : Bag **3** – Liquid supply line **24** – (open) liquid supply port **9** – First chamber **7** – Pump inlet **26** - Pump enter line **56** – Pump **1** – Pump exit line **57** – Pump outlet **27** – Second chamber **8** – (open) Patient port **18** – Patient line **5** – Patient **4**.

Figure 1B shows the "drain" phase where liquid is drained from and through the following elements : Patient **4** – Patient line **5** – (open) Patient port **10** – First chamber **7** – Pump inlet **26** – Pump enter line **56** – Pump **1** – Pump exit line **57** – Pump outlet **27** – Second chamber **8** – (open) Drain port **11** – Drain line **25** – Drain collector **6**.

The embodiment illustrated on figure 2 shows an assembly constituted by a pumping element **1** and a cartridge **2**. Both elements are fixed together but may be separated. Figure 21 shows a better view of the fixation between both elements. Preferably, the pumping element **1** is fixed to the cartridge **2** by vibration attenuation means in order to minimize the vibration on cartridge **2** when the pump is operating.

The upper face of the cartridge contains a first hub chamber **7** , a second distinct hub chamber **8** and a cavity **15** which forms part of a pressure sensor. The first chamber hub chamber **7** has three liquid supply ports **9**, one patient port **10**, one pump inlet **26** and a cavity **36** which forms part of a pressure sensor. The second hub chamber **8** has a patient port **18**, a drain port **11** and a pump outlet **27**.

The pumping element **1** comprises a pump casing **45** which contains three rollers **22** maintained around the pump casing center by a roller separator **12**. The space between the roller-roller separator element and the pump casing defines a pump race **21** in which a flexible tube **37** is placed. The flexible tube being connected with the pump enter **56** and exit **57** lines. The rollers **22** may be motor driven by a shaft **52** (not shown on figure 2) in such a way as to progressively compress the flexible tube **37** resulting thereby in a peristaltic movement along the flexible tube 37.

During the "fill" phase, liquid is supplied via one tube connector **53** and liquid supply port **9** to the first hub chamber **7**. It then enters the pump **1** through the pump inlet **26**, moves along the flexible tube **37**, enters the second hub chamber 8 through the pump outlet **27** and goes to the patient **4** via patient port **18** and patient line **5**.

During the "drain" phase, liquid leaves the patient **4**, enters the first hub chamber **7** via patient port **10**. It then enters the pump **1**, moves along the flexible tube **37**, enters the second hub chamber **8** and goes to the drain collector **6** via drain port **11**, drain tube connector **54** and drain line **25**.

It should be noted at this stage that each bag **3** may contain a specific liquid.

The cartridge **2** of figure 3 is identical to the cartridge of figure 2 with the exception of an additional cavity, namely a warmer chamber **17**, which includes a warmer port **19** and a patient port **16**. The warmer port **19** is connected to a warmer **28** (not shown on figure 3) via a warmer tube connector **55** and a warmer exit line **30**. The patient port **16** is connected to the patient line **5**. The second hub chamber **8** contains a warmer port **38** connected to a warmer **28** (not shown on figure 3) via a warmer tube connector **23** and a warmer enter line **29**.

During the "fill" phase, liquid is supplied via one tube connector **53** and liquid supply port **9** to the first hub chamber **7**. It then enters the pump **1**, moves along the flexible tube **37**, enters the second hub chamber **8**, moves into the warmer **28** via warmer port **38**, enters the warmer chamber **17** via warmer port **19** through the tube connector **55** and goes to the patient **4** via patient port **16** and patient line **5**.

As it can be seen on the embodiments of figures 2 and 3, the pump **1** is unidirectional, i.e. whatever the pumping phase is, liquid in the flexible tube **37** always moves in the same direction. This feature provides several advantages. In particular a higher precision in the liquid exchange due to the same flow speed for both the fill and drain phases and a longer life time.
It is known that peristaltic pumps are usually accurate within +/- 5%. As such, peristaltic pumps cannot be used for peritoneal dialysis since the volume which is filled within the patient cavity requires to be drained in the same amount within +/-2%, otherwise the peritoneal cavity could be overfilled (e.g. for 12 liters exchanged over the therapy, a 3% difference represents 360ml which is as much as 18% of the 2 liters contained in the peritoneal cavity for each cycle) and/or the ultra-filtration could be altered. In order to improve on the accuracy of the exchanged volume without requiring the construction of highly accurate pumps which would warranty a +/-2% accuracy, the invention provides a method whereby the conventional pump is used in a unidirectional way which insures the same accuracy for both the fill and the drain phase (usually within +/-2%) and therefore an appropriate balance of fluid. The volume filled with such a pump may be inaccurate within +/-5%, but since the same cassette with the same flow speed characteristics (namely the same flow direction) is used, the balance can be insured within +/-2% as required for the therapy. If the cassette would be used in both directions, the difference in flow speed would be within +/-5% due to the non parallel behavior of peristaltic pumps, in particular over time.

It should be noted that with the present invention, the precision in the liquid exchange is maintained even if the pump flow rate changes after a certain time due to aging of the tubing since the fill and drain are operated within a time

window which is small in comparison to the time in which the flow speed is altered by aging (e.g. a flow alteration of the pump of approximately 1% per 20 liters of fluid pumped, with exchanged volumes of approximately 2 liters per cycle). In addition, the use of the cassette in one direction enables a better control over the aging of the tubing and, therefore, a better prediction of the impact on the pumping accuracy.

Figure 4 is a transparent view of the cartridge which better shows how the different elements are connected. A cartridge bottom view is shown on figure 5. The tubing system in the lower face and the cavities of the upper face are all made within one single part, e.g. an injected part of plastic material.

Figure 6 shows an assembly including the cartridge **2** of figure 3 fixed to a pumping element **1**, a patient line **5**, supply bags **3**, a warmer enter line **29**, a warmer outer line **30** and a warmer pouch **28** which is essentially made of a fluid circuit within a plastic bag (e.g. PVC) to be put into contact with a warming plate.

Figure 6" shows a warming plate contained into a warming system where the warming pouch has a shape of a sock to be inserted onto the warming plate. The warming pouch is composed of a liquid channel which forces the liquid to be maintained within such warmer for a certain duration at a given flow rate.

Figure 7 shows a cartridge identical to the one of figure 3 where the rollers are part of the cycler rather than of the cartridge. In this embodiment, the pumping element **1** which only contains the tube and tubing race and the cartridge **2** are forming a single element.
The rollers, which are part of the cycler and therefore re-usable rather than disposable with the cardridge, have a conical shape so as to allow the rollers to be self inserted in the pump race. In this configuration the cartridge is more simple to manufacture and contains less parts. No other insertion mechanism is required, since the tube is automatically compressed on the race while the rollers are penetrating into the cartridge. As a separate matter, the use of conical rollers **22** results in a more constant speed of the liquid along the flexible tube **37**.

Figure 8 shows the assembly of figure 7 without the rollers **22** and the roller element.

Of course, other roller shapes may be used, e.g. spherical or cylindrical.

The embodiment of figure 9 only differs from the one of figure 8 in that the pump casing **45** is made out of two parts with an interface between the pumping element **1** and the cartridge **2**. This configuration offers an improved assembly process of the pump and the possibility to add means to limit the propagation of the vibrations from the pump **1** to the cartridge **2**.

Figure 10 shows a cycler **51** without cartridge **2** and pumping element **1**. It contains a driving zone which includes a motor shaft **52** for the rollers **22** and several actuators **34**. The cycler **51** also includes an air sensor **43** situated close to the patient line **5** when the cartridge **2** is inserted. The air sensor may be made of a piezo emitter and a piezo receiver.

Figure 11 represents the embodiment of figure 2 with a flexible membrane **13** covering the hub chambers **7,8** and the pressure sensor cavity **15**.

The upper face of the membrane **13** (see figure 12) contains several valve elements having a cylindrical cavity **39** and a pressure sensor area **31** with a ply **40** around its periphery. The valve elements **39** are designed to tightly close the ports when the membrane **13** moves downwardly.

On its bottom face (see figure 13) the membrane **13** contains a semi-circular flange **32** around the pressure sensor area and annular liquid tight joints.

In addition the cartridge **2** includes liquid tight joints arranged in such a manner that they allow a liquid tight connection between the cartridge **2** and the membrane **13**.

Advantageously the membrane is molded. Preferably the membrane **13** is made of silicone.

The membrane **13** is press-fitted to the cartridge **2** along its periphery with a membrane frame14 (see figure 14).

Figure 15 shows the cycler of figure 10 in an open state which includes a pump motor and a coder **42**. The rectangle **41** represents the cartridge loader.

Figure 16 shows a cartridge loader comprising cartridge loader shafts **46**, a cartridge loader frame **47**, a cartridge loader linear cam **48** and a cartridge loader motor **49**. On this figure, the two displacement parts **48'** and **48"** represent two different positions of the loader in an open and closed position only for explanation reasons.

The cartridge loading mechanism allows a tight connection between the membrane and the valves and the cartridge. In order to insure proper positioning of the cartridge onto the valve actuators, as well as pressure sensor and air sensor onto the right place, the cartridge is maintained into the loading mechanism which progressively moves the cartridge in an axis which is perpendicular to its surface. By the same movement, the axis or the rollers can be inserted in the right position to ensure proper functioning of the pump. The same movement can also insure appropriate pressure on the surfaces which requires to be maintained together, such as for tightness control on the membrane and/or tubing of the pump.

Figure 17 shows the cycler **51** of figure 10 containing a cartridge **2**. The cycler **51** has an insertion slot **50** in an open position.

Figure 18 shows the same cycler **51** but with an insertion slot in a closed position.

Figure 19 represents an actuator **34** with its plunger **35** clipped in its corresponding valve element **39** of the membrane. The actuator **34** may be a magnet or an electromagnetic element. The plunger **35** and the valve element **39** are designed to move together when the actuator is activated.

Figure 22a and 22b shows the plunger **35** and the valve element **39** in a separate position (fig. 22a) before insertion and in an activated position (fig. 22b) after insertion. One embodiment of the invention is to insure a proper insertion of the actuator head into the membrane clipping part by having the length of the part of the actuator head to be inserted into the clip of the membrane to be longer than

the possible displacement of the actuator head, so as to ensure that the actuator head is always properly inserted into the clip of the membrane. As such, in the worst case where the actuator head would be fully retracted within the actuator during the clipping translation into the membrane, the actuator head would pass the clipping equilibrium position before the end of the translation, so that the remaining translation will ensure clipping of the actuator head into the membrane.

The front view of figure 20 illustrates a pressure sensor **44** which may be used with the independent pressure sensor cavity **15** of the cartridge **2** or with the pressure sensor cavity **36** of the first hub chamber **7**. The ply **40** makes the pressure sensor less sensitive to the elasticity of the membrane **13** in the sensor pressure area. In addition, the shape of the cavity **15** shall be made such that air can be eliminated easily when fluid is passing into the cavity (e.g. by having a round shaped bottom of the cavity within the direction of the flow).

In the embodiments discussed previously, each port has a dedicated valve. This is not the case for the pump inlet and the pump outlet which are always kept open.

The invention encompasses several other features not necessarily illustrated on the figures. For instance, the cycler or the cartridge-pumping element assembly may contain a window for detecting correct positioning of the flexible tube of the pump as shown in figure 21 (circle).

When the system functions, the pressure is preferably always maintained positive with respect to the drain. This is a safety measure which avoids said contaminated liquid to potentially infect the patient.

Advantageously the liquid pressure entering and exiting the cartridge is sensed and, if necessary, the pump flow rate is corrected in accordance with the pressure difference. This pressure difference is better calculated at the initial priming phase of the system, where the pressure is directly related to the positioning of the liquid bags **3** and the patient position relative to the cycler.

Alternatively or in addition, the pump flow rate may be regulated according to a predetermined deterioration of the tubing which is known from the characteristics of the tubing.

The drain phase may be limited as to its duration in function of the drain speed, the drain speed having to be reduced when the patient peritoneal cavity pressure decreases, typically between 30 ml/min and 120 ml/min instead of a nominal 200 ml/min speed. This feature is particularly interesting because the dialysis efficiency is directly related to the time the liquid stays in the peritoneal cavity and the duration required to fully drain the peritoneal cavity may limit this time without a significant impact with regard to the peritoneal fluid characteristics. As such, one method of the invention would be to determine at which speed it is not worth continuing draining the patient entirely and rather fill the patient with fresh fluid, taking into consideration the remaining fluid volume in the peritoneal cavity which has not been expelled and expected ultra-filtration additional volume to avoid overfill. The cycles will therefore be all different, based on reaching a pre-determined drainage speed or a pre-determined decrease profile of the drainage speed, so that the efficient time of dialysis will be increased. An example of drainage speed on a patient is given in the figure **25**, where, for each column which is divided in three parts, the upper part corresponding to a limit of drainage speed at which it is, for example, not worth continuing the drainage even if the next fill volume will not be a full fill. In comparison to actual method where a tidal at (e.g. 80%) is preset, the method under the invention is adapting each drainage to the actual drainage speed, trying to empty as much as possible without compromising on the efficacy of the peritoneal dialysis. Of course some limits can be set, where a minimum of drainage volume has to be reached before such a limitation takes place for each cycle.

Another method under the present invention consists to fill always as much volume, within certain limits to be set for the patient, until a certain pressure in the peritoneal cavity is reached. As such, the peritoneal dialysis can be improved since the efficiency is related to the amount of fluid filled at every cycle. According to such method, the pump shall fill the patient until a certain pressure is reached

(e.g. 10cm water) and stop only once such pressure is reached or a certain maximum volume is reached. Accordingly, it is important to measure continuously the pressure during the dwell time to make sure that no over pressure is reached, such as due to the ultra-filtration. One possibility is also to always fill up to such a limited pressure and/or volume and drain at a certain interval thereafter a certain volume to compensate for expected ultra-filtration. Another possibility is to increase the ultra-filtration during the last cycle, by using e.g. low sodium concentrated solution.

Figure 26 illustrates another embodiment which uses peristaltic finger elements working on a hemispheric channel in the hard plastic part. The channel and the liquid distribution system are covered by a single membrane. A peristaltic pumping effect is obtained by pressing down these fingers in a sequence. This performs a digital type peristaltic pump with a high accuracy, which remains in particular independent of inlet and outlet pressure changes. Preferably the fingers are moved in a progressive way to simulate a peristaltic movement. Those fingers can be operated either individually, e.g. by electric means, or by a mechanical cam which simulates the peristaltic movement and which is rotating along the fluid channel (e.g. a rotating disk with a variable thickness which displays a wave on its surface in contact with the finger elements) . Alternatively, those fingers can be clipped onto the membrane and be operated individually in the same manner as the valves are, or by a rotating disk cam. In such last embodiment, the advantage is that the position of the membrane is perfectly known in both push and pull direction, to ensure that the peristaltic pumping is not depending on the pressure.

The embodiment of figure 27 only differs from the embodiment of figure 26 in that the membrane includes cavities to receive and guide the finger elements (e.g. by clipping means).

Preferably the membrane is biocompatible, allows a simple sealing to the liquid distribution system e.g. by welding, sticking, gluing, laser or heat melting. In addition the membrane should be made in a material avoiding the release of particles due to mechanical stress or self migration due to the material itself (e.g.

Kraton™, Santoprene™, Biopure™, Pebax™ or Polyurethane). Finally the membrane must be soft and elastic in order to properly perform valve and / or pump functionalities.

It is also possible to use multi-layer material with in inner layer (on the fluid side) which is more biocompatible and with low spallation characteristics.

In one particular embodiment, the membrane is also covering the fluid pumping channel, at 45°, to ensure possible operation with either conical rollers or ball rollers which are part of the cycler.

Figures 28 to 31 illustrates a molded frame which is adapted to cover in a tight manner the space between the hub chambers, each space above said hub chambers being covered by a flexible membrane, preferably made of injected silicone or elastic biocompatible material. In such embodiment, the molded frame and silicone or elastic biocompatible membrane can be obtained by over-molding techniques.

The system according to the present invention may furthermore include free flow preventing means which prevent the flow of fluid towards or from the liquid distribution system when it is released from the cycler.

This preventing means may be made of a mechanical clamp around the patient line, which is not clamping during the treatment will be closed automatically due to the movement of a loading mechanisms by releasing the cartridge, such as by clipping mechanism.

Figure 32 illustrates such a clamping mechanism which consists of a slotted clamping member **60** movably fixed to the liquid distribution system **2** via a flexible U shape member **61**. Figure 32 also shows a shaft **62** which is fixed to the cycler (not shown). In the illustrated position, the liquid distribution system **2** is not fixed to the cycler. When fixation occurs, the shaft **62** is inserted through the opening **65** of the flexible U shape member **61** and retained to it by a retaining lip **63**. When the liquid distribution system **2** is released from the cycler (downward movement) the bottom of the U shape member **61** is moved upwardly resulting in

a movement of the clamping member **60** in the direction of the patient line **5**. The patient line **5** will be kept closed as long as the shaft **62** is retained in the U shape member **61**. To detach the liquid distribution system **2** completely from the cycler, the shaft **62** has to pass through a releasing slot **66**.

Alternatively the patient line is closed by a special designed, so called "lip valve" which is normally closed. Due to a mechanical pin in the cycler the lip valve, as an integrated part of the membrane, will be open by simply pressed down with the pin coming from the cycler by mechanical movement.

Figures 33 to 37 show another embodiment of the invention, similar to the embodiment of figure 14a, but which differs in that the membrane **13** is not fixed by a clipping frame but by a rigid plate **67** which covers the membrane **13** over its entire surface. The rigid plate has holes **70** adapted to receive the membrane actuator clips **39** and pins **68** adapted to be fixed on the cartridge **2**. The membrane is provided with holes **69** which are designed to let the pins **68** pass through.

As can be seen on figure 37, the bottom side of the membrane **13** is provided with a flange **73** which is situated around the actuator clip **39**. The cartridge **2** surface just below the flange **73** is provided with a groove **72**. The groove **72** is adapted to receive and hold the flange **73** sufficiently enough to maintain a fluid tight connection between the membrane **13** and the cartridge **2**.

This embodiment offers several advantages, in particular an improved distribution of the forces applied to the membrane **13**.

In another embodiment of the invention (not illustrated) the system comprises one or several flow sensor(s) which is/are preferably situated close to the pump inlet and/or outlet.

The flow sensor may be of any type suitable for the intended purpose. For instance, but not exclusively, it may be of the mechanical (e.g. turbine flowmeter), mass (e.g. thermal flowmeter), electronic, magnetic or US type.